U.S. House and Senate Notification
Thursday, September 16, 2010

To: **Congressional Health Staff**

From: **Amy Hall**
Director, Office of Legislation
Centers for Medicare & Medicaid Services

Subject: **Request for Comments on Process for CMS-FDA Parallel Review of Medical Products**

The Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) today jointly announced a proposal for parallel review of certain medical products and invited public comments on the plan. The process under consideration by the agencies would allow for concurrent evaluations of pre-market, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. Through concurrent review of relevant evidence, the process could reduce the time between FDA marketing approval and CMS national coverage determinations, and accelerate Medicare beneficiaries' access to innovative technologies.

In a Federal Register notice to be published tomorrow, September 17, the agencies are soliciting public comments on which products would be appropriate for parallel review, how dual reviews should be timed and coordinated, and how such a process should be implemented. The agencies are also announcing their intent to create a pilot program of parallel review for medical devices to begin after both agencies have reviewed the public comments on the notice. A memorandum of understanding concerning the exchange of data and information has been completed between the two agencies.

More information on this announcement is available on CMS' coverage website at http://www.cms.gov/center/coverage.asp and on the FDA website at http://www.fda.gov.

If you have any questions, please contact the CMS Office of Legislation. Thank you.